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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,421	12/07/1999	ALAN A. DAVIS	AHP92038-2-C	7663

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/457,421	DAVIS ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/05/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 and 28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/05/2005 has been entered.

Corrected Filing Receipt

2. Applicant's request to correct first Applicant's Name and correspondence address has been noted by the Office.

Status of Claims

3. Claims 1-25, 27 and 41 are cancelled. Claims 26 and 28-40 are pending and under examination.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 26 and 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung et al.[1] in view of Davis et al.[2]

6. Claims 26, 28-31 and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chanda et al. (Int. Rev. Immunol., 1990; 7(1): 67-77. or Virology, 1990; 175: 535-547; in the alternative) in view of Davis et al., U.S. Patent No. 4920209.

In response to the rejections set forth in the record, Applicant submits that neither Hung et al. nor Chanda et al. teach or describe the presently claimed method because neither Hung et al. nor Chanda et al. provided in vivo data or description to suggest to one of skill in the art that an Ad7-env construct would in fact elicit an immune response in any mammal and that neither Hung et al. nor Chanda et al. teach or suggest administering any booster dosages of the recombinant adenovirus as presently claimed.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is reminded that this is an obviousness type rejection, not an anticipatory rejection. In an anticipatory rejection, the references must teach or describe the claimed method to render the claimed method unpatentable. However, this is an obviousness rejection. Thus, neither Hung et al. nor Chanda et al. have to teach or describe the claimed method to render the claimed method unpatentable.

In the instant, the Office recognizes that neither Hung et al. nor Chanda et al. teach nor suggest administering any booster dosages of the recombinant adenovirus as presently claimed. However, based on the knowledge generally available to one of

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[1] Hung et al. Adenovirus vaccine strains genetically engineered to express HIV-1 or HBV antigens for use as live recombinant vaccines. Nat. Immun Cell Growth Regul, 1990; Vol. 9, 160-164.
[2] Davis et al., U.S. Patent No. 4920209.

ordinary skill in the art, it would have been prima facie obvious for one of ordinary skill in the art to have used various methodology of administrating the composition, such as in a prime and boost methodology. One of ordinary skill in the art at the time the invention was made would be motivated to do so to arrive at an administration methodology that would render the most beneficial immune response against HIV-1 infectivity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because in order to arrive at a administration methodology that would render the most beneficial immune response against HIV-1 infectivity, one of ordinary skill in the art would have necessarily use various methodology of administrating the composition as part of routine experimentation.

Furthermore, as previously stated, neither Hung et al. nor Chanda et al. need to provide in vivo data to suggest to one of skill in the art that an Ad7-env construct would in fact elicit an immune response in any animal. Hung et al. and Chanda et al. provided sufficient description of the Ad7-env construct to suggest to one of ordinary skill in the art that the Ad7-env construct would in fact elicit an immune response in any animal. In the instant, Hung et al. and Chanda et al. teach that the administration of the same adenovirus construct, though with a different antigen, induces an antibody response to the antigen that is present in the construct. This teaching suggests to one of ordinary skill in the art that the administration of the Ad7-env construct would also be capable of inducing an antibody response to the envelope glycoprotein, which would necessarily induce an immune response against HIV infection.

Additionally, the Office appreciates the summary that Applicant provided in Applicant's submission regarding Applicant's discovery. In the summary, Applicant states that Applicant clearly demonstrates that the claimed adenovirus construct are immunogenic in mammals, and protects non-human primates against HI-1 challenge. While the Office does appreciate the summary, however, the summary does not change the status of the rejection. Applicant is reminded that the claims are directed to a method of producing an immune response against HIV-1 infection. The claims are not directed to a method of providing protection against HIV-1 infection. Had it be that the claims are directed to a method of providing protection against HIV-1 infection, the reference(s) that are cited by the Office must necessarily provide an insight on the protective efficacy of the composition or the protective efficacy that can be ascertained of the composition via a unique method of administration. However, this is not instantly present in the claims. Thus, the reference(s) cited by the Office need not to provide any protective efficacy insight. However, because the claims do require that a production of an immune response against HIV-1 infection, the references must provide an insight on the production of an immune response against HIV-1 infection. In the instant, such insight can be readily deduced from the teachings of the reference(s). The reference(s) teaches that the same vector construct as those recited in the claims, having a different antigen, is capable of inducing an antibody response against said antigen. Thus, the a vector construct that Hung et al. and Chanda et al. teach, which is the same as those recited in the claims, would also be capable of inducing an antibody response against said antigen.

In response to Applicant's obvious to try argument, Applicant is reminded that a prima facie showing of obviousness is based upon what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 U.S.P.Q. 209 (C.C.P.A. 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 U.S.P.Q. 545 (C.C.P.A. 1969). In this case, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to have used various methodology of administrating the composition, such as in a prime and boost methodology. One of ordinary skill in the art at the time the invention was made would be motivated to do so to arrive at a methodology that would render the most beneficial immune response against HIV-1 infectivity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because in order to arrive at a administration methodology that would render the most beneficial immune response against HIV-1 infectivity, one of ordinary skill in the art would have necessarily use various methodology of administrating the composition as part of routine experimentation.

In addition, it is noted that Applicant is relying on the state of the art at the time the invention was made to assert that one of ordinary skill in the art would not have been motivated by any of the cited references to administer an Ad-env construct to a human to induce an immune response or would the skilled artisan have had a reasonable expectation of success for doing so based on the teachings provided in the specification, wherein the primary basis for Applicant's assertion is the enablement

rejection that was previously issued to Applicant. In response to this submission, Applicant is reminded that this is an obviousness rejection. This is not an enablement rejection. The factors, such as (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims, that are required of an enablement rejection are not required for an obviousness rejection. The factors that are required for an obviousness rejection are:

(A) Determining the scope and contents of the prior art;

(B) Ascertaining the differences between the prior art and the claims in issue;

(C) Resolving the level of ordinary skill in the pertinent art; and

(D) Evaluating evidence of secondary considerations.

In the instant case, all these factors are present in the obviousness rejection issued by the Office. Addition, Applicant's is requested to note that none of the factors includes the state of the art at the time of filing.

Furthermore, the claimed invention is directed at a method of inducing an immune response against HIV-1, not a method of treating or preventing HIV infection, which is the focus of the enablement rejection that is set forth in the previous office action. Ergo, Applicant's submission is not found persuasive.

Conclusion

7. No claim is allowed.

8. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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E.Le